United States Patent Searching Strategy,
Relevance Criteria and Reporting Information Fields
(provisional 02/17/2017)

Search Strategy

The goal of the patent search is to identify every United States Patent that includes claims of toxicity in excess of expected additive response for the pesticide active ingredient proposed for registration when applied with other pesticide chemicals. It is recommended that submissions to EPA related to United States patents regarding claims of toxicity in excess of expected additivity include documentation of the search strategy. In order to establish documentation of the patent search process, the following reporting fields for the search strategy are suggested:

1. Chemical identifiers used in the search

   At a minimum, EPA recommends that such searches utilize the IUPAC chemical name, Chemical Abstracts Number, chemical structure, chemical common name and synonyms, and trade names as search terms

2. Keywords relative to the claim of toxicity in excess of theoretical additivity

   EPA recommends the following search terms, as a minimum: synergy, synergistic, synergism, excess toxicity, interaction, and Colby.

3. Databases searched

   Patent information data sources include, but are not limited to: Google Patents, United States Patent and Trademark Office official search engine, World Patent Index, and Chemical Abstracts. EPA recognizes that other patent information sources, such as a company's own records, may also supply U.S. patents relevant to the goals of the patent search.

Relevance Criteria

Criteria 1 through 4 below are used to establish whether a United States Patent contains information relevant to determining if any information exists requiring data evaluation.

Criterion 1: The patent contains some form of empirically based comparative analysis of effects.

Criterion 2: Patent or other mixture toxicity information involves the testing of effects in taxa that are included in ecological risk assessments: mammals, birds, terrestrial macroinvertebrates, fish, aquatic macroinvertebrates, terrestrial and aquatic plants.

Criterion 3: Reported effects are direct measures on the taxon under consideration.

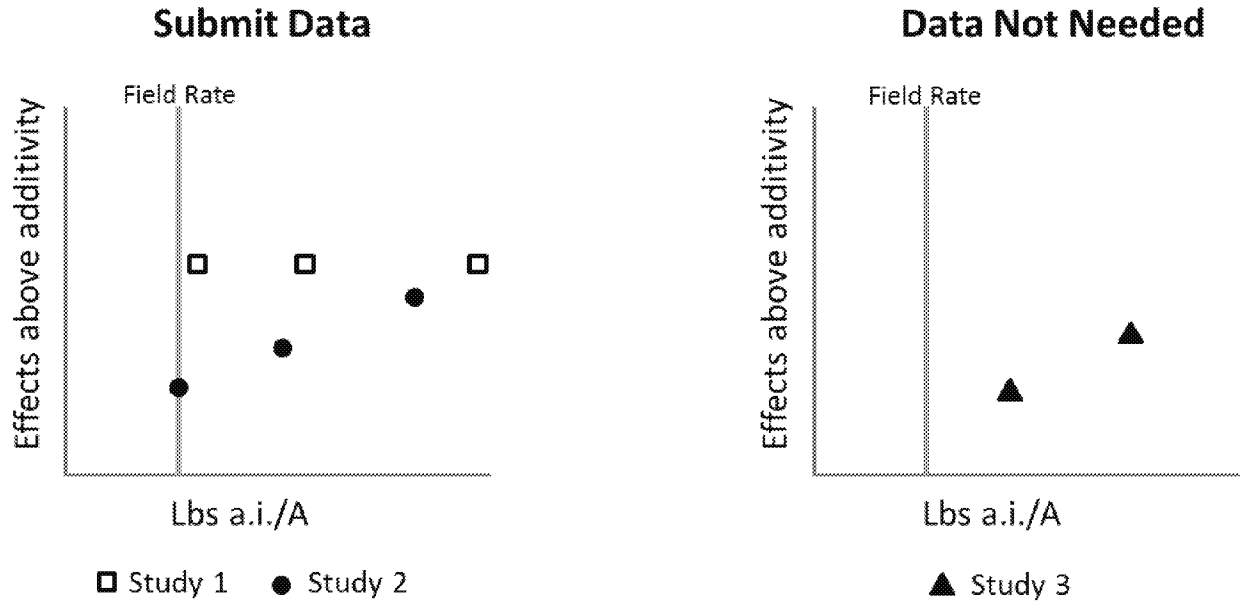
Examples include: animal survival, animal counts, signs of herbicide damage to plants

Criterion 4: Patent mixture toxicity information involves the testing for effects using the active ingredient under regulatory consideration.

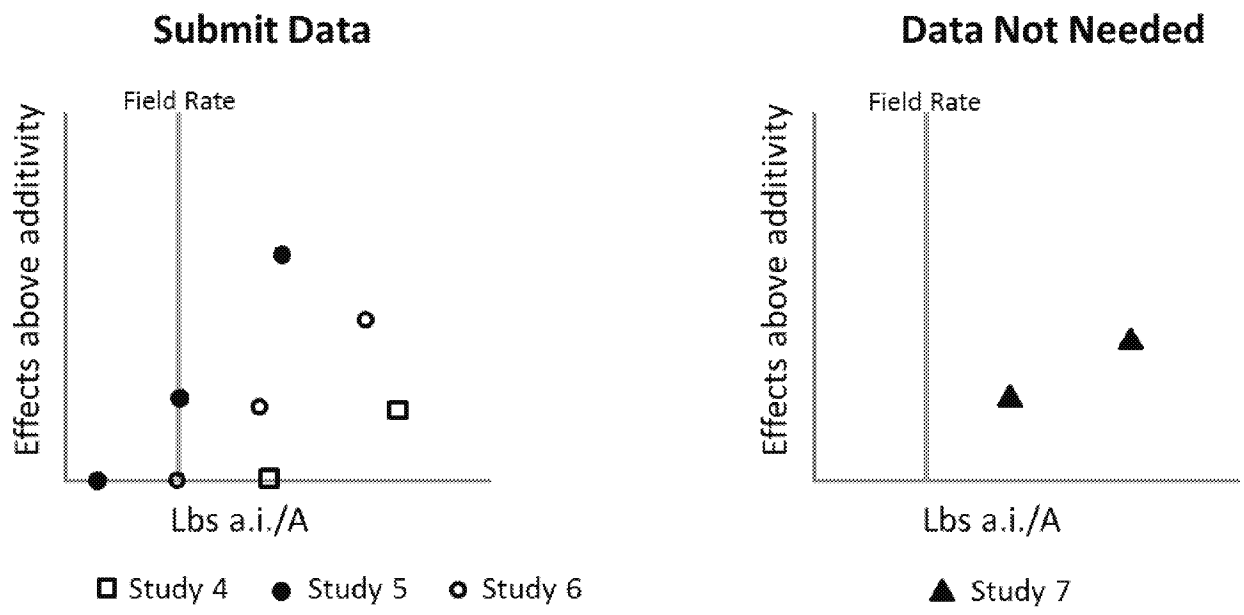
Studies not meeting criteria above are documented with, 1) United States patent identification number, and 2) rationale for exclusion from further data reporting.

United States patent documents not excluded by the above relevance criteria are subject to reporting of relevant data within the limitations below. The underlying data and methods description for patent reported data meeting the following criteria (5-7, pages 2-3) represent the minimum submission to EPA. Reporting fields are described under Fields for Underlying Patent Data Submissions (page 4). EPA encourages registrants to submit additional background summary information. Examples of additional information might include but not be limited to: 1) summarizing the extent to which additional testing has not identified observations of toxicity in excess of additivity; and 2) additional physical chemical, biochemical, mechanism of action information relevant to the patent claims

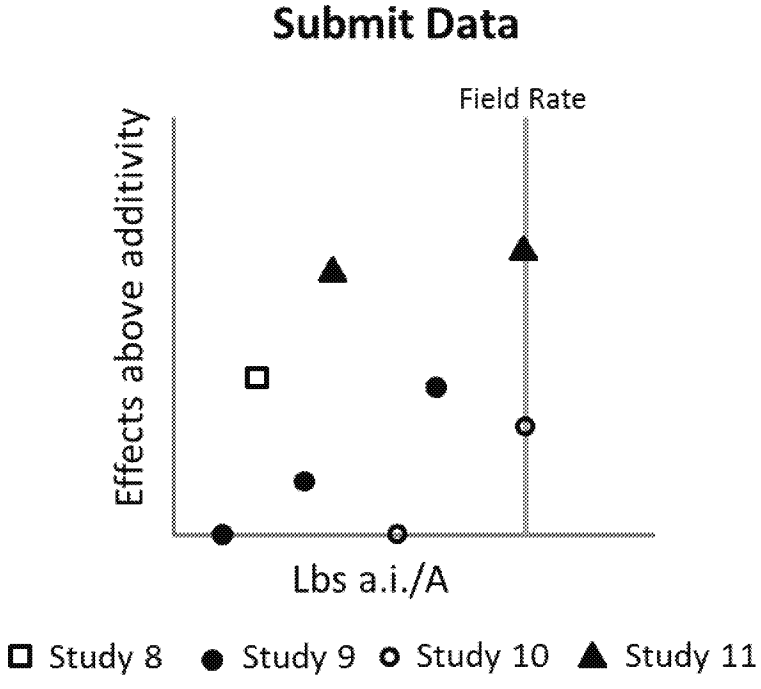
Criterion 5: The patent claims toxicity in excess of additivity in three or more treatments ***at and above*** the (current or proposed) labeled field application rate;



Criterion 6: There are two or more treatments where the patent claims toxicity in excess of additivity in one or more treatments at/above the (current or proposed) labeled field application rate but at least one treatment in the progression did not show synergy;



Criterion 7: The patent claims toxicity in excess of additivity in one or more treatments ***at or below*** the (current or proposed) labeled field application rate.



Information Fields for Underlying Patent Data Submissions

General design of the experiment. At a minimum report:

Field versus laboratory/greenhouse

Date and Duration of in-life portion

Locations of the testing areas

Block design

Observation methods/measurement methods

Replicates/Controls

Endpoints assessed

Identifiers for individual test runs if multiple experiments were performed, including unique data collector identifiers

Any information relative to the power or accuracy of observation method of effects (e.g., any summary reporting on the minimum detectable effect or observer precision of detection for observations of efficacy)

The identity of active ingredients:

Ratios of active ingredients evaluated

Identification of the test substances (e.g., TGAI versus end use product)

Identification of any test solution components (e.g., solvents, surfactants, diluents)

Application method/rates/dose progressions evaluated including any blank control or other test solution controls

The observation data reported for each treatment/control and each date (days after treatment) of observation for the individual and combined active ingredient effects

Description of the mathematical method employed to establish baseline combined expected toxicity/efficacy for the patent

Statistical methods used to identify significant departures from expected combined toxicity/efficacy

Relevant labeled field rates of all active ingredient components tested